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Response To Restriction Filed On April 18, 2007

Amendments to the Claims:

1. (Original) A pharmaceutical composition, comprising:

a water-soluble, acid-labile drug enteric-coated with a enteric coating material that

dissolves at pH above about 5.2.

2. (Original) The pharmaceutical composition of claim 1, wherein the solubility of the drug

is above 1 mg/ml in water or aqueous solution.

3. (Original) The pharmaceutical composition of claim 1, wherein the solubility of the drug

is above 10 mg/ml in water or aqueous solution.

4. (Original) The pharmaceutical composition of claim 1, wherein the drug is labile at pH

lower than 5.0.

5. (Original) The pharmaceutical composition of claim 1, wherein the drug is labile at pH

lower than 2.0.

(Original) The pharmaceutical composition of claim 1, wherein the drug is a cytidine 6.

analog.

7. (Original) The pharmaceutical composition of claim 6, wherein the cytidine analog is 5-

azacytidine or decitabine.

8. (Original) The pharmaceutical composition of claim 1, wherein the drug is a 2'-

deoxyadenosine analog.

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9. (Original) The pharmaceutical composition of claim 8, wherein the 2'-deoxyadenosine

analog is pentostatin, fludarabine, or 2-chloro-2'-deoxyadenosine.

10. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material is pH-sensitive and dissolves at pH above about 5.5.

11. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material is pH-sensitive and dissolves at pH above about 6.4.

12. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material is pH-sensitive and dissolves in normal human jejunum juice.

13. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material is pH-sensitive and the pharmaceutical composition substantially disintegrates in an

aqueous medium at or above pH 5.5 within 1 hour.

14. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material is pH-sensitive and the pharmaceutical composition substantially disintegrates in an

aqueous medium at or above pH 5.5 within 30 minutes.

15. (Original) The pharmaceutical composition of claim 1, wherein the coating material

comprises an agent selected from the group consisting of cellulose phthalates, EUDRAGIT

polymers, polyvinylacetate phthalate, SHELLAC, and cellulose acetate phthalate.

16. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material comprises EUDRAGIT L100.

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17. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material comprises EUDRAGIT L100-55.

18. (Original) The pharmaceutical composition of claim 1, wherein the enteric coating

material further comprises triacetin and TWEEN 80.

19. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical

composition does not substantially disintegrate in an acidic, aqueous medium at pH 1.0-3.0 for at

least 1 hour.

20. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical

composition does not substantially disintegrate in an acidic, aqueous medium at pH 1.2-1.5 for at

least 2 hours.

21. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical

composition disintegrates substantially in an aqueous medium at pH 5.2-7.5 within 30 minutes.

22. (Original) The pharmaceutical composition of claim 1, wherein the amount of the

enteric-coating material is 1-8% w/w in the composition.

23. (Original) The pharmaceutical composition of claim 1, wherein the pharmaceutical

composition is in a form of tablet.

24. (Original) The pharmaceutical composition of claim 23, wherein the hardness of the

tablet without the enteric-coat is at least 5 kp.

(Original) The pharmaceutical composition of claim 1, wherein the concentration of the 25.

drug is 0.1-10% w/w in the composition.

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- 26. (Original) The pharmaceutical composition of claim 1, wherein the drug is contained in a drug core that is enteric-coated with the coating material.
- 27. (Original) The pharmaceutical composition of claim 26, further comprising:
 a seal-coating material that coats the surface of the drug core and seals the drug from the moisture.
- 28. (Original) The pharmaceutical composition of claim 27, where the seal-coating material comprises hydroxy propylmethylcellulose.
- 29. (Original) The pharmaceutical composition of claim 27, where the seal-coating material comprises hydroxy propylmethylcellulose, TWEEN 80 and triacetin.
- 30. (Original) The pharmaceutical composition of claim 1, further comprising:buffer salt in an amount sufficient to maintain the pH of the local environment to be 5.2-7.0 when the pharmaceutical composition is dissolved in the GI tract.
- 31. (Original) The pharmaceutical composition of claim 30, wherein the buffer salt is sodium or potassium phosphate.
- 32. (Original) The pharmaceutical composition of claim 1, further comprising: one or more pharmaceutically acceptable excipient selected from the group consisting of diluent, lubricant, disintegrant, glidant or retention-enhancing excipient.
- 33. (Original) The pharmaceutical composition of claim 32, wherein the one or more excipient is blended with drug and the mixture of which forms a drug core.

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34. (Original) The pharmaceutical composition of claim 33, wherein the drug core is directly

coated with the enteric coat.

35. (Original) The pharmaceutical composition of claim 33, wherein the drug core is first

sealed with a seal-coating material and then coated with the enteric coat.

36. (Original) The pharmaceutical composition of claim 32, wherein the diluent is selected

from the group consisting of microcrystalline cellulose, lactose monohydrate, starch, gelatin,

gum, tragacanth, calcium phosphate, sucrose, mannitol, sorbitol, and dextrose.

37. (Original) The pharmaceutical composition of claim 32, wherein the lubricant is selected

from the group consisting of magnesium stearate, stearic acid, and calcium stearate.

38. (Original) The pharmaceutical composition of claim 32, wherein the disintegrant is

selected from the group consisting of croscarmellose sodium, polyvinylpyrrolidone,

polyvinylpolypyrrolidone, agar, alginic acid, a salt of alginic acid, sodium alginate, sodium

starch glycolate, and starch.

39. (Original) The pharmaceutical composition of claim 32, wherein the disintegrant is

selected from the group consisting of colloidal silica, tale, cornstarch, and syloid.

40. (Original) The pharmaceutical composition of claim 32, wherein the retention-enhancing

excipient is selected from the group consisting of bioadhesive polymers, mucoadhesive

polymers, swelling hydrogels, and viscogenic agents.

41. (Original) The pharmaceutical composition of claim 32, wherein the retention-enhancing

excipient is selected from the group consisting of carboxyvinyl polymer, methyl cellulose,

hydroxypropyl methylcellulose, and polycarbophil.

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42. (Original) The pharmaceutical composition of claim 32, wherein the one or more

excipient is a combination of microcrystalline cellulose, starch, colloidal silica and stearic acid.

43. (Original) The pharmaceutical composition of claim 42, wherein the drug and the one or

more excipient are blended together to form a drug core which is then enteric-coated with the

enteric coating material.

44. - 48. (Canceled).

49. (Original) A pharmaceutical composition, comprising: a camptothecin compound

enteric-coated with an enteric coating material that dissolves at pH above about 5.2.

50. (Original) The pharmaceutical composition of claim 49, wherein the enteric coating

material is pH-sensitive and dissolves at pH above about 5.8.

51. (Original) The pharmaceutical composition of claim 49, wherein the enteric coating

material is pH-sensitive and dissolves at pH above about 6.4.

52. (Original) The pharmaceutical composition of claim 49, wherein the enteric coating

material is pH-sensitive and dissolves in normal human jejeunum juice.

53. (Original) The pharmaceutical composition of claim 49, wherein the enteric coating

material is pH-sensitive and dissolves at pH above about 5.8.

(Original) The pharmaceutical composition of claim 49, wherein the enteric coating 54.

material is selected from the group consisting of cellulose phthalates, EUDRAGIT polymers,

polyvinylacetate phthalate, SHELLAC, and cellulose acetate phthalate.

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55. (Original) The pharmaceutical composition of claim 49, wherein the enteric coating

material is EUDRAGIT L100.

56. (Original) The pharmaceutical composition of claim 49, wherein the enteric coating

material is EUDRAGIT L100-55.

57. (Original) The pharmaceutical composition of claim 49, wherein the enteric coating

material further comprises triacetin and TWEEN 80.

58. (Original) The pharmaceutical composition of claim 49, wherein the camptothecin

compound is selected from the group consisting of 9-nitro-20(S)-camptothecin, 9-amino-20(S)-

camptothecin, 9-methyl-camptothecin, 9-chloro-camptothecin, 9-flouro-camptothecin, 7-ethyl

camptothecin, 10-methyl-camptothecin, 10-chloro--camptothecin, 10-bromo-camptothecin, 10-

fluoro-camptothecin, 9-methoxy-camptothecin, 11-fluoro-camptothecin, 7-ethyl-10-hydroxy

camptothecin, 10,11-methylenedioxy camptothecin, and 10,11-ethylenedioxy camptothecin, and

7-(4-methylpiperazinomethylene)-10,11-methylenedioxy camptothecin.

59. (Original) The pharmaceutical composition of claim 49, wherein the camptothecin

compound is water-insoluble.

60. (Original) The pharmaceutical composition of claim 49, wherein the camptothecin

compound is 9-nitro-20(S)-camptothecin.

61. (Original) The pharmaceutical composition of claim 49, further comprising one or more

pharmaceutically acceptable excipient selected from the group consisting of diluent, lubricant,

disintegrant, glidant or retention-enhancing excipient.

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62. (Original) The pharmaceutical composition of claim 61, wherein the one or more

excipient is blended with the drug and the mixture of which forms a drug core.

63. (Original) The pharmaceutical composition of claim 62, wherein the camptothecin

compound is water-insoluble and the drug core is directly enteric coated with the enteric coating

material.

64. (Original) The pharmaceutical composition of claim 62, wherein the camptothecin

compound is water-soluble, and the drug core is first sealed with a seal-coating material and then

coated with the enteric coat.

65. (Original) The pharmaceutical composition of claim 61, wherein the diluent is selected

from a group consisiting of microcrystalline cellulose, lactose monohydrate, starch, gelatin, gum,

tragacanth, calcium phosphate, sucrose, mannitol, sorbitol, and dextrose.

66. (Original) The pharmaceutical composition of claim 61, wherein the lubricant is selected

from the group consisting of magnesium stearate, stearic acid, and calcium stearate.

67. (Original) The pharmaceutical composition of claim 61, wherein the disintegrant is

selected from the group consisting of croscarmellose sodium, polyvinylpyrrolidone,

polyvinylpolypyrrolidone, agar, alginic acid, a salt of alginic acid, sodium alginate, sodium

starch glycolate, and starch.

68. (Original) The pharmaceutical composition of claim 50, wherein the disintegrant is

selected from the group consisting of colloidal silica, talc, cornstarch, and syloid.

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- 69. (Original) The pharmaceutical composition of claim 50, wherein the retention-enhancing excipient is selected from the group consisting of bioadhesive polymers, mucoadhesive polymers, swelling hydrogels, and viscogenic agents.
- 70. (Original) The pharmaceutical composition of claim 51, wherein the retention-enhancing excipient is selected from the group consisting of carboxyvinyl polymer, methyl cellulose, hydroxypropyl methylcellulose, and polycarbophil.
- 71. (Caneled).
- 72. (Cancled).